DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

THE SURGEON GENERAL, DEPARTMENT OF THE ARMY
KENNETH BERTRAM, MD, PHD
PRINCIPAL ASSISTANT FOR ACQUISITION
1430 VETERANS DRIVE
FORT DETRICK MD 21702-5009

April 16, 2015

Re: K143592
Trade/Device Name: Gamma Phage Lysis Assay For The Identification Of Bacillus Anthracis
Regulatory Class: unclassified
Product Code: NVQ
Dated: December 17, 2014
Received: December 18, 2014

Dear Dr. Bertram:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M. Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143592

Device Name
GAMMA PHAGE LYSIS ASSAY FOR THE IDENTIFICATION OF BACILLUS ANTHRACIS

Indications for Use *(Describe)*
The Gamma Phage assay is a lytic phage assay specific for Bacillus anthracis. The Gamma Phage assay (common name) can be used on suspect non-hemolytic, aerobic, gram-positive, "ground-glass"- appearing colonies from sheep blood agar in conjunction with other markers and testing for the identification of Bacillus anthracis. The assay is not intended for screening of blood or plasma donors.

Use of this assay is limited to designated laboratories within the Laboratory Response Network (LRN) and Department of Defense (D0D).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Gamma Phage Lysis for the Identification of Bacillus anthracis

Submitted by:	Office of Surgeon General, Department of Army
Sponsor's Representative	Kenneth A. Bertram, MD, PhD Principal Assistant for Acquisition U.S. Army Medical Research and Materiel Command (USAMRMC) 1430 Veterans Drive Fort Detrick, MD 21702-5009
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Manufacturer:	Mark Wolcott, PhD MT(ASCP) United States Army Medical Research Institute of Infectious Diseases (USMRIID) Diagnostic Systems Division 1425 Porter Street Ft. Detrick, MD 21702 Telephone: 301-619-4738
Date Prepared:	04/09/2015

510(k) Summary

Trade Name:	Gamma Phage Lysis for the Identification of *Bacillus anthracis*
Common Name:	*Bacillus anthracis* Culture, Controls
Classification Name:	Bacteriophage And Controls, *B. anthracis* Lysis
Submission Type:	Special 510k
Device Class:	Unclassified
Product Code:	NVQ
Predicate Device:	K051794 *Gamma Phage Lysis for the Identification of Bacillus anthracis*

Indications for Use

The Gamma Phage assay is a lytic phage assay specific for *Bacillus anthracis*. The Gamma Phage assay (common name) can be used on suspect non-hemolytic, aerobic, gram-positive, "ground-glass"-appearing colonies from sheep blood agar in conjunction with other markers and testing for the identification of *Bacillus anthracis*. The assay is not intended for screening of blood or plasma donors.

Use of this assay is limited to designated laboratories within the Laboratory Response Network (LRN) and Department of Defense (D0D).

Device Description and Comparison

The gamma phage is a lytic bacteriophage which binds to specific cell-surface components of susceptible bacteria. Their DNA is injected into the bacterium. The gamma phage replicate within the bacterium and produce PlyG lysine (2), resulting in lysis of the infected cell and release of phage. The release of newly synthesized phage leads to another round of phage infection and lysis.

Materials Supplied:

- *Bacillus anthracis* Gamma Phage Suspension, 0.5 ml
- Positive Control, *Bacillus anthracis* Pasteur Strain Spore Suspension, 1.0 ml
- Negative Control, *Bacillus cereus* Spore Suspension, 1.0 ml

Materials required but not supplied:

- 5% Sheep Blood Agar plate
- Inoculating loops, 1μl and 10 μl
- Aerosol resistant pipette tips
- Disinfectant

Equipment required:

- Pipettor, 5-50 μl

- Incubator, 35+/- 2 ºC
- Biological Safety Cabinet, Class II
- Refrigerator, 2-8 ºC

The only modification that was made is a change to the positive control strain (listed above), from the specified Pasteur strain, to the Sterne strain. The change in positive control strain does not impact the performance of the assay and does not substantially alter the 510k Premarket Notification Submission.

Substantial Equivalence:

The modified Gamma Phage Lysis for the Identification of Bacillus *anthracis* has the same characteristics to those which previously received 510(k) concurrence:

- Have the same indication for use
- Use the same operating principle
- Incorporate the same materials , and equipment
- Has the same specimen collection and preparation instruction

The assay differs in that a new positive control strain, from specified Pasteur strain, to the Sterne stain.

510(k) Summary

Table of Differences Compared to Original Submission (K051794)

Feature	**K051794** Predicate Device	**K143592** Proposed Device
Positive Control	Bacillus anthracis Pasteur strain spore suspension 1.0 ml (BC3132)	Bacillus anthracis Sterne strain viable lyophilized cells (BC3366) Colorado Serum Company (19102) Anthrax Spore Vaccine – 1.0 ml suspension of viable Bacillus anthracis Sterne strain 34F2 spores
Negative Control	Bacillus cereus spore suspension 1.0 ml (BC3133)	Bacillus cereus spore suspension 1.0 ml (BC3133) - same Bacillus cereus lyophilized cells (BC3367) ATCC 14579 – Bacillus cereus freeze-dried (lyophilized)
Reporting – Capsule Staining Techniques	A positive gamma phage result, in conjunction with a positive result for capsule, is considered confirmatory identification of B. anthracis. Capsule may be demonstrated by colony morphology on bicarbonate agar after incubation in enhanced CO_2 or by staining techniques (India ink, M'Fadyean, or capsule DFA).	A positive gamma phage result, in conjunction with a positive result for capsule, is considered confirmatory identification of B. anthracis. Capsule may be demonstrated by colony morphology on bicarbonate agar after incubation in enhanced CO_2 or by staining techniques (India ink or M'Fadyean). Difference - Capsule DFA removed.